



FEB 13 2006

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7.0 Summary of The Technological Characteristics of The Device

The Powder Free Nitrile Examination Gloves, Blue, Non Sterile are summarized with the following technological characteristics compared to ASTM or equivalent standards.

| CHARACTERISTICS | STANDARDS | DEVICE PERFORMANCE |
|-----------------------|---|--|
| Dimension | D 6319-00a ^{E3} | Meets |
| Physical Properties | D 6319-00a ^{E3} | Meets |
| Freedom from Pinholes | D 6319-00a ^{E3} FDA 21 CFR 800.20 | Meets |
| Powder Residue | D 6319-00a ^{E3} D6124 - 01 | < 2 mg/glove |
| Biocompatibility | Primary Skin Irritation in Rabbits | Passes (No primary skin irritation) |
| | Dermal Sensitization | Passes (No contact sensitizer) |

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves or for most devices cleared by the 510 (k) processes.

10.0 Conclusion

It can be concluded that The Powder Free Nitrile Blue Examination Gloves, Blue, Non Sterile will perform according to the gloves performance standards referenced in Section (7) above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed device.



510 (K) SUMMARY

1.0 Submitter:

Name : PT MAHAKARYA INTI BUANA
Address : Jl. Sei Belumai, Desa Dalu 10 A Dusun I No. 18
Tanjung Morawa – 20362
SUMUT – INDONESIA
Phone No. : +62-61-7944880
Fax No. : +62-61-7944882

Date of Summary Prepared:

2.0 Contact Person:

Name : Mr. Sasitharan Nair
Phone : +62-61-7944880
Fax No. : +62-61-7944882

3.0 Name or the device:

Trade Name : 1) Senstouch and
2) Multiple or Customers' Trade Name
Device Name : Powder Free Nitrile Examination Gloves, Blue, Non
Sterile
Common Name : Examination Gloves
Classification Name : Nitrile Examination Gloves (Class I)

4.0 Identification of The Legally Marketed Device:

Class I Nitrile Examination Gloves, 80LZA, powder free, that meets all the requirements of ASTM standard D 6319-00a^{E3} and FDA 1000 ml Water Leak Test.

5.0 Description of The Device

The Powder Free Nitrile Examination Gloves, Blue, Non Sterile meets all the requirements of ASTM standard D 6319-00a^{E3} and FDA 1000 ml Water Leak Test.

6.0 Intended Use of The Device

The Powder Free Nitrile Examination Gloves, Blue, Non Sterile is a disposable device intended for medical purposes that is worn on the examiner's to prevent contamination between patient and examiner.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. P Sasitharan Nair
Quality Regulation Manager
PT. MAHAKARYA INTI BUANA
Jl. Sei Belumai, Desa Dalu 10 A Dusun I No. 18
Tanjung Morawa-20362
SUMUT-INDONESIA

Re: K053657

Trade/Device Name: Powder Free Nitrile Examination Gloves, Non-Sterile (Blue)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: November 21, 2005
Received: December 5, 2005

Dear Mr. Nair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 053657

Device Name:

POWDER FREE NITRILE EXAMINATION GLOVES, NON-STERILE (BLUE)

Indications For Use:

Powder Free Nitrile Examination Gloves, Non - Sterile is a disposable device and made of Synthetic Polymer that exhibits rubber like characteristics intended for medical purposes that is worn on the examiner's hands of finger to prevent contamination between patient and examiner.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley M. Murphy, MD 2/11/06
(Director, ODE)
Division of Anesthesiology, Central Hospital,
University of California, San Diego

510(k) Number

K 053657

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